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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,427

09/30/2005

Andrew David Miller

CU-4022 RJS

6762

26530 7590 07/13/2009
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EXAMINER

PUTTLITZ, KARL J

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

07/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,427	Applicant(s) MILLER ET AL.	
	Examiner KARL J. PUTTLITZ	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>various</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The rejection under section 112, first paragraph is withdrawn in view of the amendments deleting prevention from the method claims.

The rejection under section 112, second paragraph is maintained in part below:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 was rejected since the claim recited that the PHG group is "derived" from the listed groups. Applicant's amended the claim to delete the term "derived". However, the structure of the compounds is still indefinite since it is unclear how the PHG groups are bound to the XYZ-C(O) group. Therefore the structure of the PHG group remains unclear.

Claim 61 indicates that p is from 1 to 3. However, it is unclear how p can be 3 in the case of where PHG is defined as phospholipid or a lysophospholipid, where, in those cases, at least 1 -OH group would be occupied by a phosphate group. Applicants respond that this is permissible. However, the claim still does not clarify how p can exceed the available places where the PHG can bind to glycerol.

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The following is a new ground of rejection: X^2 , X^3 , X^4 , in claims 92-95, or at least one cis double bond in claim 96 in claims lack antecedent basis in claim 87.

The claims have been clarified such that the proviso now states that Z is a C1-C6 alkyl group when Y is S and PHG is a phosphatidylethanolamine phospholipid or phosphatidylethanolamine lysophospholipid. However, in view of this amendment, the following is a new ground of rejection under section 112, first paragraph:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-82, 84-96, 98-101, 116-119 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims include the proviso: wherein Z is a C1-C6 alkyl group when Y is S and PHG is a phosphatidylethanolamine phospholipid or phosphatidylethanolamine lysophospholipid.

However, the specification does not include this sub-genus of compounds and thus the specification does not show that the inventor were in possession of this sub-genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

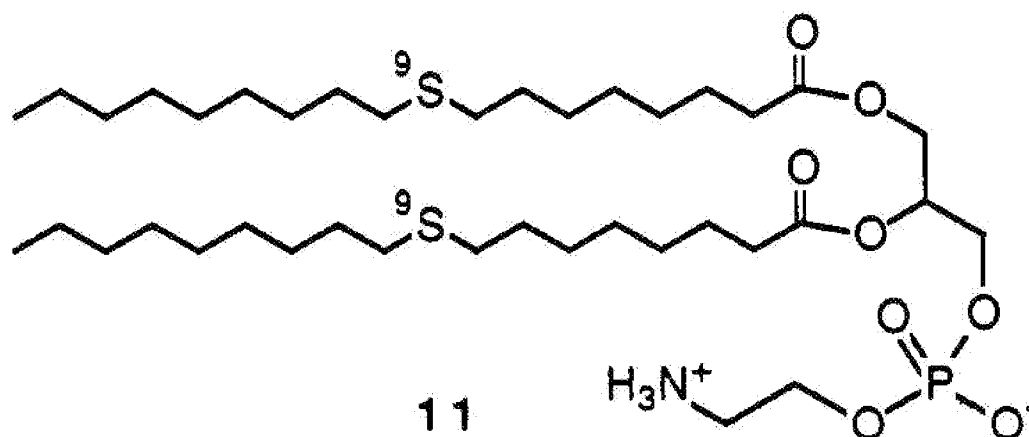
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61-64, 67, 84 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruoxin et al. *Sulfur-substituted Phosphatidylethanolamines*. J.Org.Chem. 1993, 58, 1952-1954.

The instant claims are drawn to a lipid compound of formula (I) $(XYZ-C=O)_p$ -PHG with substituents as defined therein, a combination of a liposome and a compound of formula (I), a method for the production of a lipid compound of formula (I), a cosmetic formulation comprising a lipid compound of formula (I), a method of making the compound of formula (I), a pharmaceutical composition comprising a compound of formula (I) and a method of treating a plurality of disorders selected from, *inter alia*, Syndrome X, obesity, comprising administering to a subject in need thereof an effective amount of a compound of formula (I) or a pharmaceutically acceptable salt thereof.

Ruoxin et al. teach sulfur-substituted phosphatidylethanolamines of the formula 11 (see page 1952) and the synthesis routes to make the diacylglycerol-sulfur-containing phosphatidylethanolamines (pp 1952-1954).

Ruoxin et al. teach the following compound:

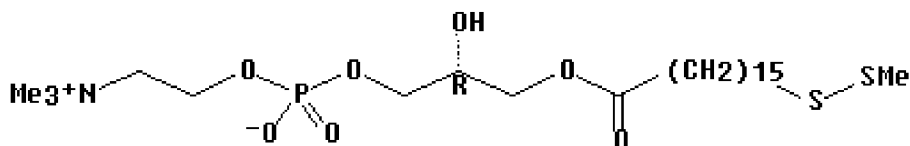


The rejection under section 102 over Ruoxin is maintained, since the PHG in Ruoxin is phosphatidylcholine, and outside of the proviso that Z is a C1-C6 alkyl group when Y is S and PHG is a phosphatidylethanolamine phospholipid or phosphatidylethanolamine lysophospholipid, should this proviso stand as supported in the specification.

The rejection under section over Lehninger is withdrawn.

Claims 65, 66, 80 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Runquist et al., *Biochimica et Biophysica Acta, Biomembranes* (1988), 940(1), 10-2 (Runquist).

Runquist teaches the following compound:



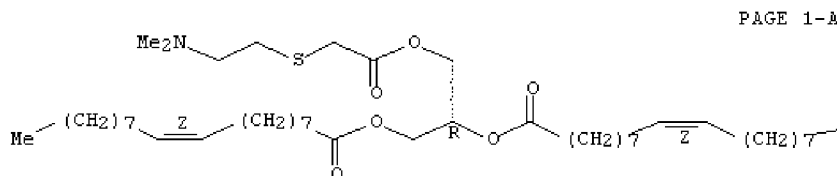
See attached CAS online citation 1988:524492 [retrieved 17 November 2008] from STN; Columbus, OH, USA.

The rejection under section 102 over Runquist is maintained, since the PHG in Runquist is phosphatidylcholine, and outside of the proviso that Z is a C1-C6 alkyl group when Y is S and PHG is a phosphatidylethanolamine phospholipid or phosphatidylethanolamine lysophospholipid, should this proviso stand as supported in the specification.

The rejection to claims 89 and 90 over 2000030444 is withdrawn, but now applied to claims 1, 87, 88, 94-96:

Claim 1, 87, 88, 94-96 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 2000030444.

WO 2000030444 teaches the following compound:



See attached CAS online citation 133:22412 [retrieved 17 November 2008] from STN; Columbus, OH, USA.

WO 2000030444 teaches the recited compounds when PHG is a diacylglycerol.

The double patenting rejection remains outstanding:

The double patenting rejection remains pending:

Provisional Obviousness Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 61- 67 and 71-119 is maintained on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over *claims 1,9,13,20-23,32,33,39-44 and 48 of copending Application No. 10/484855 (US2004/0219202)*. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant lipid compound of formula (I) is the same as the copending application's lipid compound when the instant substituents of formula (I) match. Illustratively, when $X=C_6-C_{24}$ containing one or more double bonds; $Y=O$ or CH_2 , $Z=C_{1-10}$ alkyl group; PHG=polar head group and the use of said lipid compound for the treatment of a disorder.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-

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0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan, can be reached at telephone number (571) 272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Karl J. Puttlitz/

Primary Examiner, Art Unit 1621